IFW

P/546-279 REISSUE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Patent Application of:

William STERN

Reissue Serial No.: 10/774,358

Reissue Appln. Filed: February 5, 2004

Reissue of U.S. Patent No.: 6,440,392

Issued: August 27, 2002

For: NASAL CALCITONIN FORMULATION

Date: November 6, 2006

Confirmation No.: 8408

Group Art Unit: 1616

Examiner: Mina Haghighatian

Mail Stop Reissue
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUMMARY OF EXAMINER INTERVIEW
PURSUANT TO M.P.E.P. §713.04

Applicant submits this interview summary in accordance with M.P.E.P. §713.04. The Examiner is thanked for her interview summary mailed October 16, 2006, with which Applicant is in substantial agreement.

A telephone interview was held with the Examiner on October 5, 2006. Participating in the interview, on behalf of the applicant, were William O. Gray III (Reg. No. 30,944) and Mark A. Farley, (Reg. No. 33, 170). The interview was conducted following the filing of Amendments and Remarks by Applicant in response to the Office Action dated May 11, 2006.

New matter rejections were discussed first. With regard to the range of 250 to 350 mOsm/liter in claims 15, 31 and 43-44, the Examiner agreed that the range was originally found in the claims of the parent application, but requested that Applicant also add the range to the body of the specification. Applicant agreed to so amend the specification.

As to the range of "10-25 mM" for the bioavailability enhancing agent, as stated in claims 13-17, 20, 21 and 24-44, the Examiner noted that Table 1, in column 5 of the original patent, appears to support the 10-25 mM range only for citric acid and not necessarily for the combination of citric

acid and citric acid salt. The same objection was noted by the examiner regarding the term "aggregate," in claims 13 and 15, and for the same reason. Applicant indicated that a declaration may be submitted to better show how Table 1 supports the claimed range when a combination of citric acid and citric acid salt is used. The remaining "new matter" objection related to the word "such" in the clause "aggregate concentration of all such bioavailability enhancing agents" in claims 13 and 15. Applicant agreed to remove the word "such" because that word is not believed by Applicant to be grammatically necessary or to affect the claim scope.

The art rejections were discussed next. It was urged (1) that the Dua reference teaches the desirability of hypertonic or hypotonic solutions rather than the isotonic solutions claimed by Applicant in all of the claims reciting 250-350 mOsm, and (2) that the Kagatani reference disclosed citric acid/citrate levels significantly outside of the ranges set forth in Applicant's claims. The Examiner agreed to consider withdrawing rejections based on Dua or Kagatani, but indicated there might be other references of record that she would consider using in a future Office Action. The foregoing discussion of Dua and Kagatani is relevant to all claims because all claims are subject to at least one-art rejection that includes Kagatani or Dua.

Finally, claims rejected over Grebow alone (claims 13-14, 17, 20-23, 34 and 40-42) were discussed. Applicant argued that the citric acid and/or citric acid salt recited in the rejected claims defined a patentably distinct specie which was neither disclosed nor suggested by the broad generic disclosure of Grebow for the reasons discussed in Applicant's latest written response to Office Action. Agreement was not reached on that issue.

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Reissue, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 6, 2006:

William O. Gray, III
Name of applicant, assignee or Registered Representative

Signature

November 6, 2006
Date of Signature

WOG:MAF:db

Respectfully submitted,

William O. Gray III
Registration No.: 30,944
OSTROLENK, FABER, GERB & SOFFEN, LLP
1180 Avenue of the Americas
New York, New York 10036-8403
Telephone: (212) 382-0700